PD ISO/TS 9002:2016

BSI Standards Publication

Quality management systems — Guidelines for the application of ISO 9001:2015

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National foreword

This Published Document is the UK implementation of ISO/TS 9002:2016.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance procedures.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2016

ISBN 978 0 580 91749 3

ICS 03.120.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 November 2016.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 9002:2016

TECHNICAL SPECIFICATION

ISO/TS 9002

First edition
2016-11-01

Quality management systems — Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001:2015

Reference number
ISO/TS 9002:2016(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

Introduction

This document has been developed to assist users to apply the quality management system requirements of ISO 9001:2015[28] *Quality management systems – Requirements*.

This document provides guidance, with a clause by clause correlation to Clauses 4 to 10 of ISO 9001:2015[28], however it does not provide guidance on ISO 9001:2015[28], Annexes A and B . Where there is direct correlation between list items (i.e. bullet points) in a clause in ISO 9001:2015[28] and the guidance, this is indicated within the clause of this document.

This document gives examples of what an organization can do, but it does not add new requirements to ISO 9001. The examples in this document are not definitive and only represent possibilities, not all of which are necessarily suitable for every organization.

ISO 9001 contains requirements that can be objectively audited or evaluated. This document includes examples, descriptions and options that aid both in the implementation of a quality management system and in strengthening its relation to the overall management system of an organization. While the guidelines in this document are consistent with the ISO 9001 quality management system model, they are not intended to provide interpretations of the requirements of ISO 9001 or be used for audit or evaluation purposes.

As the requirements of ISO 9001 are generic, this document can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance can vary based on factors such as the size or the complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

Risk is the level of uncertainty inherent in a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are determined, considered and controlled throughout the design and use of the quality management system.

Risk-based thinking has been implicit in previous editions of ISO 9001 in such requirements as determining the type and extent of control for external providers based on the effect of the product that is going to be provided, or taking corrective action based on the potential effect of an identified nonconformity.

In addition, in previous editions of ISO 9001, a clause on preventive action was included. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its quality objectives. Some need more careful and formal planning and control than others.

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010[23] provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In some cases, an organization might have a formal risk management process in place that is required by customers or statutory and regulatory requirements. In such circumstances, the organization can adapt its formal risk management process to meet the intent of the requirements in ISO 9001 concerning risks and opportunities.

In addition to ISO 9001:2015[28], Annex A, ISO has published a number of other quality management standards and informative resources which can assist the user and provide information on additional implementation methods, including:

— the ISO handbook: ISO 9001:2015[28] *for Small Enterprises – What to do ? Advice from ISO/TC 176*

— the ISO 9001 Auditing Practices Group (APG) papers: www.iso.org/tc176/ISO9001AuditingPracticesGroup[31]

— public information on the ISO/TC 176/SC2 website: https://committee.iso.org/tc176sc2[30]

— the ISO handbook: *The Integrated Use of Management System Standards*[29].

Additional standards and documents are listed in the Bibliography.

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Quality management systems — Guidelines for the application of ISO 9001:2015

1 Scope

This document provides guidance on the intent of the requirements in ISO 9001:2015[28], with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2015[28], *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015[28] apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this subclause is to understand the external and internal issues that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management system. The organization should be aware that external and internal issues can change, and therefore, should be monitored and reviewed. An organization might conduct reviews of its context at planned intervals and through activities such as management review.

Information about external and internal issues can be found from many sources, such as through internal documented information and meetings, in the national and international press, websites, publications from national statistics offices and other government departments, professional and technical publications, conferences and meetings with relevant agencies, meetings with customers and relevant interested parties, and professional associations.

Examples of external and internal issues relevant to the organization's context can include, but are not limited to:

a) external issues related to:

   1) economic factors such as money exchange rates, economic situation, inflation forecast, credit availability;

   2) social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;

   3) political factors such as political stability, public investments, local infrastructure, international trade agreements;

   4) technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;

   5) market factors such as competition, including the organization's market share, similar products or services, market leader trends, customer growth trends, market stability, supply chain relationships;

   6) statutory and regulatory factors which affect the work environment (see ISO 9001:2015[28], 7.1.4) such as trade union regulations and regulations related to an industry;

b) internal issues related to:

   1) overall performance of the organization;

   2) resource factors, such as infrastructure (see ISO 9001:2015[28], 7.1.3), environment for the operation of the processes (see ISO 9001:2015[28], 7.1.4), organizational knowledge (see ISO 9001:2015[28], 7.1.6);

   3) human aspects such as competence of persons, organizational behaviour and culture, relationships with unions;

   4) operational factors such as process or production and service provision capabilities, performance of the quality management system, monitoring customer satisfaction;

   5) factors in the governance of the organization, such as rules and procedures for decision making or organizational structure.

At the strategic level, tools such as Strengths, Weaknesses, Opportunities and Threats analysis (SWOT) and Political, Economic, Social, Technological, Legal, Environmental analysis (PESTLE) can be used. A simple approach can be useful for organizations dependent on the size and complexity of their operations, such as brainstorming and asking "what if" questions.

4.2 Understanding the needs and expectations of interested parties

The intent of this subclause is to ensure that the organization considers the relevant requirements of relevant interested parties, beyond just those of its direct customers. The intention is to focus on only those relevant interested parties which can have an impact on the organization's ability to provide products and services that meet requirements. While not directly stated in ISO 9001, the organization could consider its external and internal issues (see ISO 9001:2015[28], 4.1) before, and to assist in, determining its relevant interested parties.

The list of relevant interested parties can be unique to the organization. The organization can develop criteria for determining relevant interested parties by considering their:

a) possible influence or impact on the organization's performance or decisions;

b) ability to create risks and opportunities;

c) possible influences or impact on the market;

d) ability to affect the organization through their decisions or activities.

EXAMPLE 1 Examples of relevant interested parties that can be considered relevant by an organization include, but are not limited to:

— customers;

— end users or beneficiaries;

— joint venture partners;

— franchisors;

— owners of intellectual property;

— parent and subsidiary organizations;

— owners, shareholders;

— bankers;

— unions;

— external providers;

— employees and others working on behalf of the organization;

— statutory and regulatory authorities (local, regional, national or international);

— trade and professional associations;

— local community groups;

— non-governmental organizations;

— neighbouring organizations;

— competitors.

To understand the needs and expectations of relevant interested parties, several activities and methods can be carried out. They include working with those responsible for the processes or by using methods that allow the gathering of information. Methods include, but are not limited to:

— reviewing orders received;

— reviewing statutory and regulatory requirements with compliance or legal departments;

— lobbying and networking;

— participating in relevant associations;

— benchmarking;

— market surveillance;

— reviewing supply chain relationships;

— conducting customer or user surveys;

— monitoring customer needs, expectations and satisfaction.

EXAMPLE 2 Examples of relevant interested party requirements include, but are not limited to:

— customer requirements regarding conformity, price, availability or delivery;

— contracts which have been entered into with customer or external providers;

— industry codes and standards;

— agreements with community groups or non-governmental organizations;

— statutory and regulatory requirements for the product or service provided, and those that affect the organization's ability to provide that product or service;

— memoranda of understanding;

— permits, licenses or other forms of authorization;

— orders issued by regulatory agencies;

— treaties, conventions and protocols;

— agreements with public authorities and customers;

— voluntary principles or codes of practice;

— voluntary labelling or environmental commitments;

— obligations arising under contractual arrangements with the organization;

— policies for employees.

The information resulting from these activities should be considered in planning the quality management system (see ISO 9001:2015[28], Clause 6).

The organization should be aware that the relevant interested parties and their relevant requirements can be different for the different products and services provided, and can change due to unforeseen circumstances or intentional reactions to markets.

The organization should have robust systems in place to monitor and review the relevant requirements of its interested parties. Monitoring and reviewing can be done by using the organization's processes related to customer requirements, design and development of products and services, and (at a more strategic level) during management review.

4.3 Determining the scope of the quality management system

The intent of this subclause is to determine the boundaries of the quality management system so that it is defined in a manner that helps the organization meet requirements and the intended results of the system.

For ISO 9001:2015[28], 4.3, bullets a) to c), the scope should be established based on:

a) the external and internal issues as determined by the requirements of ISO 9001:2015[28], 4.1;

b) the relevant requirements of relevant interested parties (such as regulators as well as customers) as determined in accordance with the requirements in ISO 9001:2015[28], 4.2;

c) the products and services provided by the organization.

In determining the scope, the organization should also establish the boundaries of the quality management system by considering such issues as:

— the infrastructure of the organization;

— the organization's different sites and activities;

— commercial policies and strategies;

— centralized or externally provided functions, activities, processes, products and services.

All requirements of ISO 9001> are considered applicable unless they do not have an effect on the organization's ability to provide a product or deliver a service that meets requirements or on its enhancement of customer satisfaction.

In determining the application of requirements in ISO 9001, the organization should consider each individual requirement, and not just decide that a whole clause is not applicable. At times, some of the requirements may be applicable in a clause, or all of the requirements within a clause may, or may not, be applicable.

The scope should be maintained as documented information. The scope should include details of the products and services covered. It should also include justification for any requirements that are determined not to be applicable. This documented information can be maintained in whatever method the organization determines to meet its needs, such as a manual or a website.

4.4 Quality management system and its processes

4.4.1 The intent of this subclause is to ensure that the organization determines the processes needed for its quality management system in accordance with ISO 9001. This includes not only the processes for production and service provision, but also the processes that are needed for the effective implementation of the system, such as internal audit, management review and others (including processes that are performed by external providers). For example, if the organization determines the need for a process for monitoring and measuring resources, the process will need to meet the requirements of ISO 9001:2015[28], 7.1.5. The level to which processes need to be determined and detailed can vary according to the context of the organization and the application of risk-based thinking – taking into consideration the extent to which the process affects the organization's ability to achieve its intended results, the likelihood of problems occurring with the process and the potential consequences of such problems.

A process is a set of interrelated or interacting activities that use inputs in order to deliver intended results. For ISO 9001:2015[28], 4.4.1, bullets a) to h):

a) the organization should determine the inputs required and the outputs expected from its processes; inputs required for the processes should be considered from the viewpoint of what is required for the implementation of the processes as planned; expected outputs should be considered from the viewpoint of what is expected either by the customers or the subsequent processes; inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge);

b) when determining the sequence and interaction of these processes, the links with the inputs and outputs of the previous and subsequent processes should be considered; the methods for providing details of the sequence and interaction of the processes depends on the nature of the organization; different methods can be used, such as retaining or maintaining documented information (e.g. process maps or flow diagrams), or a more simple approach, such as a verbal explanation of the sequence and interaction of the processes;

c) to make sure that processes are effective (i.e. deliver the planned results), the process control criteria and methods should be determined and applied by the organization; criteria for monitoring and measurement could be process parameters, or specifications for products and services; performance indicators should be related to monitoring and measurement, or can be related to the organization's quality objectives (criteria); other methods for performance indicators include, but are not limited to, reports, charts or the results of audits;

d) the organization should determine the resources needed for processes, such as people, infrastructure, environment for the operation of the processes, organizational knowledge and monitoring and measuring resources (see ISO 9001:2015[28], 7.1); considerations on the availability of resources should include the capabilities and constraints of existing internal resources and those that are obtainable from external providers;

e) the organization should assign the responsibilities and authorities for its processes by first determining the activities of the process and then determining the persons who will perform the activity; the responsibilities and authorities can be established in documented information, such as organization charts, documented procedures, operational policies and job descriptions, or by using a simple approach of verbal instructions;

f) the organization should ensure that any actions needed to address risks and opportunities associated with the processes are implemented (see ISO 9001:2015[28], 6.1);

g) the organization should consider the performance data obtained through the review of criteria established for monitoring and measuring; analyse and evaluate this data; and implement any changes needed to ensure that these processes consistently achieve their intended results;

h) the organization can use the results of analysis and evaluation to determine the necessary actions for improvement; improvements can be made at the process level (e.g. by reducing variations in the way an activity is performed) or at the quality management system level (e.g. by reducing the paperwork associated with the system, allowing persons to concentrate more on managing the processes).

4.4.2 The intent of this subclause is to ensure that the organization determines the extent of documented information that is needed.

Documented information is information required to be controlled and maintained by an organization and the medium on which it is contained.

The appropriate person (e.g. process owner, process output owner, process control person) should review what information is used for the process to perform consistently to deliver the intended output. For information (e.g. procedures, work instructions, visual aids, information and communication systems, drawings, specifications, metrics, reports, key performance indicators [KPIs], meeting minutes, representative samples, verbal conversations) that is used, an analysis/review of the value to support the process needs to be carried out. The result will be the decision as to which information will be treated as documented information. For example, when top management does strategic planning, they could consult and review relevant information on the internet, such as reports on the current and future status of the organization's industry sector that have been developed by governmental agencies and other relevant parties. This information should not be considered as documented information, as it is available from the public domain. In contrast, a business plan that includes quality objectives, risk and opportunities, strategies, among other relevant elements (e.g. the organization's mission, vision, values and process map) would need to be considered as documented information.

It is up to the organization to specify the different types of documented information needed to support the operation of its processes and its quality management system. In determining the type and extent of documented information needed, the organization should evaluate its own needs and apply risk-based thinking. It should also give consideration to its size, activities, types of products or services, complexity of its processes, resources, etc., as well as the potential consequences of nonconformities.

While ISO 9001 specifies the use of documented information in a number of its requirements, there can be a need for the organization to have additional documented information (such as documented procedures, websites, work instructions, manuals, regulations, standards, forms, guides, computer software, telephone "apps") to control the operation of its processes.

Some of the organization's documented information will need to be reviewed periodically and be revised to be kept up to date. ISO 9001 uses the phrase "maintain documented information" in reference to this type of documented information.

Other documented information needs to be retained unchanged (unless a correction is authorized) to demonstrate conformity and to have confidence that processes are being carried out as planned, or to demonstrate whether or not requirements are being fulfilled (this type of documented information is frequently referred to as a "record"). ISO 9001 uses the phrase "retain documented information" in reference to this type of documented information. This type of documented information is frequently

related to customer requirements, statutory and regulatory requirements, or the organization's own requirements, for retaining documented information.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

The intent of this subclause is to ensure that top management demonstrate leadership and commitment by taking an active role in engaging, promoting, and ensuring, communicating and monitoring the performance and effectiveness of the quality management system. The ways it can be applied are based on various factors, such as the size and complexity of an organization, management style and organizational culture.

For an organization, "top management" may include, for example, the chief executive officer, managing director, general manager, chairman, board of directors, executive directors, managing partner(s), single owner, partner(s) and senior executives/managers. Top management has the power to delegate authority and provide resources within the organization. If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Each organization has different needs and its own specific solution that will be decided by top management. It is important for top management to ensure that the organization's quality management system processes are integrated with its business processes.

For ISO 9001:2015[28], 5.1.1, bullets a) to j), this includes:

a) top management making it clear that they understand and are accountable for the effectiveness of the quality management system by taking responsibility for its activities and by being able to explain the results that are achieved; although certain authorities and responsibilities (see ISO 9001:2015[28], 5.3) can be delegated, the accountability remains with top management;

b) ensuring that the quality policy (see ISO 9001:2015[28], 5.2) and quality objectives (see ISO 9001:2015[28], 6.2) are established while giving consideration to the strategic direction and context of the organization; the quality policy and quality objectives might be established or reviewed during routine meetings of top management, such as those for strategic planning or management review purposes;

c) ensuring that the organization's quality management system processes are integrated and managed within its overall business processes, and not treated as "add-on" or conflicting activities;

d) promoting the process approach and risk-based thinking, for example, by ensuring the effective interaction between processes, with a systematic approach designed to achieve effective flow of inputs and outputs and co-operation in addressing risks and opportunities;

e) monitoring the current and projected workload and schedules to ensure that adequate quality management system resources (persons, tools, equipment etc.) are provided, when and where needed;

f) communicating, via internal meetings, email, personal discussions, organizational intranet, etc., the value and benefits of the quality management system and adherence to its requirements;

g) ensuring that the quality management system achieves its intended results by monitoring its outputs; at times, actions can be required to correct or improve the system or its component processes and top management should ensure that whatever actions are needed are properly assigned and resourced;

h) engaging, directing and supporting persons in the organization to contribute to the effectiveness of the quality management system by communicating with them (see ISO 9001:2015[28], 7.4); this could include top management serving as the champion of projects when improvements are needed and encouraging employees and others to participate as members of improvement teams;

i) promoting improvement while ensuring that information and recommendations from audits, other evaluations and management reviews (see ISO 9001:2015[28], 9.3) are communicated to the responsible persons (this can also help to demonstrate the value and benefits of improvements);

j) providing support and guidance to persons in other relevant managerial roles to help them demonstrate leadership as it applies to their own specific areas of influence; this could include mentoring and supporting them in making specific decisions which help the organization conform better to requirements, or to drive improvements when needed.

Effective leadership and commitment can lead to better understanding by the persons in the organization of how they contribute to the quality management system, which can help the organization to consistently achieve its intended results.

5.1.2 Customer focus

The intent of this subclause is to ensure that top management visibly demonstrates leadership and commitment in maintaining the organization's focus on meeting customer requirements and enhancing customer satisfaction.

Customers are generally the people or organizations that purchase the organization's products and services; however, it can also mean the individuals or organizations such as citizens, clients, patients, students, etc. who are the recipients of the organization's products and services.

Top management needs to ensure that effective processes are in place to determine customer requirements and statutory and regulatory requirements related to the organization's products and services, and that these requirements are understood. In many cases, a focus for on-time delivery performance and on customer complaints can provide information on any actions that might be necessary in order to achieve or improve customer satisfaction.

Top management needs to ensure that appropriate actions are implemented to address risks and opportunities, so that expected results are consistently achieved; if they are not, then a Plan-Do-Check-Act (PDCA) approach should be followed to ensure that responsibilities are assigned for implementing further improvements, until customer needs and expectations are achieved.

Top management can focus on enhancing customer satisfaction by using the results of analysis and evaluation of customer satisfaction data (see ISO 9001:2015[28], 9.1.2). As a result of this analysis, top management might direct a change in the customer related processes and the operations of the organization, including the allocation of resources.

5.2 Policy

5.2.1 Establishing the quality policy

The intent of this subclause is to ensure that a quality policy is established which aligns with the strategic direction of the organization, including the organization's overall understanding of what quality means to itself and for its customers. The quality policy describes the intentions and direction of the organization as formally expressed by its top management.

For ISO 9001:2015[28], 5.2.1(bullets a) to d), the established quality policy should:

a) be appropriate to the organization and support its strategic direction;

b) provide a framework for setting objectives (which means any claims in the quality policy should be measurable);

c) give a commitment to the organization satisfying applicable requirements, such as customer or statutory and regulatory requirements;

d) give a commitment to continual improvement of the quality management system.

In order to establish the quality policy, inputs such as the following can be considered:

— a clear understanding of the context of the organization, including the current performance of its management system and the needs and expectations of its relevant interested parties;

— the organization's strategic direction, based on its mission, vision, guiding principles and core values;

— the level and type of future improvements needed for the organization to be successful;

— the expected degree of customer satisfaction;

— the resources needed to meet intended results;

— the potential contributions of relevant interested parties.

5.2.2 Communicating the quality policy

The intent of this subclause is to ensure that the quality policy is communicated, understood and applied by persons in the organization so they are able to contribute to the effectiveness of the quality management system, and that it is available to relevant interested parties.

The organization should ensure that the quality policy is readily available and maintain it as documented information. In order to maintain the quality policy, the organization should review it periodically to determine if it is still appropriate to the purpose of the organization. This could be done, for example, as part of the management review process (see ISO 9001:2015[28], 9.3).

The organization needs to ensure that the quality policy is clearly understood throughout the organization. This can be achieved by considering the requirements for awareness (see ISO 9001:2015[28], 7.3) and communication (see ISO 9001:2015[28], 7.4) by persons at different levels within the organization. The quality policy can be communicated by different methods such as via noticeboards, screensavers, by the organization's website, or during routine meetings.

The organization should make the quality policy available, as appropriate, to relevant interested parties such as external providers, partners, customers and regulatory agencies. This can be done on request or by publishing the quality policy on a website.

5.3 Organizational roles, responsibilities and authorities

The intent of this subclause is for top management to assign the relevant roles in relation to the quality management system, in order to ensure the effectiveness and the achievement of intended results. Top management will need to establish specific responsibilities and authorities for the roles and ensure that persons of the organization understand and are aware of their assignments through effective communications activities.

Responsibilities and authorities can be assigned to one or more persons. They should be able to make decisions and effect change to the area and/or processes to which they have been assigned. It is essential to emphasise that although authority can be delegated, the overall responsibility and accountability for the quality management system remains with top management.

For ISO 9001:2015[28], 5.3, bullets a) to e), responsibilities and authorities should be assigned for the following:

a) ensuring that the quality management system conforms to the requirements of ISO 9001 for specific roles, such as internal auditors, or for management review;

b) ensuring that processes are delivering their intended outputs; this action could be assigned to more than one person who would each have different responsibilities, such as monitoring the quality objectives, determining if the processes are achieving their intended results, or conducting internal audits;

c) reporting on the performance of the quality management system; this reporting is typically carried out as part of the management review process (see ISO 9001:2015[28], 9.3); one person might be assigned responsibility for coordinating the reporting, with other persons being responsible for reporting on specific processes of the quality management system;

d) promoting a customer focus (see ISO 9001:2015[28], 5.1.2); this responsibility is typically assigned to the person who is responsible for communicating with customers and ensuring that any issues are resolved; this person is frequently part of the customer service or quality function;

e) maintaining the integrity of the quality management system when changes are made such as the implementation of a new enterprise resource planning (ERP) system, the decision to outsource the design and development process, growth due to new market opportunities, restructuring the organization, a merger or an acquisition; this responsibility is typically assigned to the person(s) who is (are) responsible for ensuring that the overall quality management system is maintained and who has (have) the ability to ensure that changes are not planned without considering their potential impact.

In some organizations, there could be a limited number of persons with the required competence available to carry out the tasks required; it could be useful to plan for sharing roles and responsibilities. Such plans are valuable during holidays, when managers are away from the facility or in cases of accident or illness.

Top management should determine how to communicate the relevant roles, responsibilities and authorities. This could be through the use of relevant documented information, e.g. job descriptions, work instructions, duty statements, organization charts, manuals, procedures.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 The intent of this subclause is to ensure that when planning the quality management system processes, the organization determines its risks and opportunities and plans actions to address them. Its purpose is to prevent nonconformities, including nonconforming outputs, and to determine opportunities that might enhance customer satisfaction or achieve an organization's quality objectives.

When determining the risks and opportunities for the quality management system, the external and internal issues (see ISO 9001:2015[28], 4.1) as well as relevant interested parties' requirements (see ISO 9001:2015[28], 4.2) should be considered. Examples of the risks that the quality management system will not achieve its objectives include the failure of processes, products and services to meet their requirements, or the organization not achieving customer satisfaction. Examples of opportunities include the potential to identify new customers, to determine the need for new products or services and to bring them to market, or to determine the need for revising or replacing a process by the introduction of new technology in order for it to become more efficient.

When examining its opportunities, the organization should first determine and assess the potential risks to the quality management system associated with them; the results should be used when making the decisions on whether or not to implement them.

For ISO 9001:2015[28], 6.1.1, bullets a) to d), in determining its risks and opportunities, the organization should focus on:

a) giving confidence that the quality management system can achieve its intended result(s);

b) enhancing desirable effects, and the creation of new possibilities (by improving the efficiency of its activities, developing or applying new technologies, etc.);

c) preventing or reducing undesired effects (through risk reduction or preventive actions);

d) achieving improvement to ensure product and service conformity and enhancing customer satisfaction.

This is adopting an approach of risk-based thinking and the organization should consider the application of this approach to the processes required for its quality management system.

There is no requirement in ISO 9001 to use formal risk management (in accordance with ISO 31000 [19]) in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010[23] provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In determining risks and opportunities, the organization can consider using the outputs of techniques such as SWOT or PESTLE. Other approaches can include techniques such as Failure Mode and Effects Analysis (FMEA); Failure Mode, Effects and Criticality Analysis (FMECA); or Hazard Analysis and Critical Control Points (HACCP). It is for the organization to decide which methods or tools it should use. Simpler approaches include techniques such as brainstorming, Structured What If Technique (SWIFT) and consequences/probability matrices.

The application of risk-based thinking can also help an organization to develop a proactive and preventive culture focused on doing things better and improving how work is done in general.

There are various situations where risks and opportunities should be considered, for example strategy meetings, management reviews, internal audits, different kinds of meetings on quality, meetings to set quality objectives, the planning stages for the design and development of new products and services, and the planning stages for production processes.

6.1.2 The intent of this subclause is to ensure that the organization plans actions to address its determined risks and opportunities (see ISO 9001:2015[28], 6.1.1), implements the actions, analyses and evaluates the effectiveness of the actions taken. The actions should be based on the potential impact on the conformity of products and services or on customer satisfaction, and need to be incorporated into both the quality management system and its processes, as is appropriate. For example if the organization has a single source provider of a critical raw material, then it should consider investing in developing a new source.

The actions that an organization can take to address risks will depend on the nature of the risk, for example:

a) avoiding the risk, by no longer performing the process where the risk can be encountered;

b) eliminating the risk, for example, by using documented procedures to assist persons in the organization with less experience;

c) taking the risk to pursue an opportunity, such as investing in new capital equipment to launch a product line where the return on investment is unknown;

EXAMPLE Examples of actions to address opportunities include adopting new technologies and seeking new customers or markets.

d) sharing the risk, for example, by working with the customer to facilitate the advance purchase of raw materials when production levels are unknown;

e) taking no action, where the organization accepts the risk itself, based on its potential effect or the cost of the needed action.

The organization may consider the need for documented information on risks and opportunities, both for its quality management system and for its processes (see ISO 9001:2015[28], 4.4.1).

6.2 Quality objectives and planning to achieve them

6.2.1 The intent of this subclause is to ensure that the organization establishes quality objectives and plans appropriate actions to achieve them.

Quality objectives should be established at relevant functions, levels and processes, as appropriate, to ensure the effective deployment of the organization's strategic direction and its quality policy. For example, quality objectives might be set at an operational level, for the procurement function or the design process.

For ISO 9001:2015[28], 6.2.1, bullets a) to g), the quality objectives should:

a) be consistent with the quality policy, i.e. when establishing the quality objectives, the organization needs to use the quality policy as an input; for example, if the organization has a statement in its quality policy to exceed its customer expectations, then it could have a quality objective that relates to on-time delivery or customer complaints;

b) be measurable, for example by specifying a period of time or a defined quantity that needs to be achieved; the quality objective can be measurable by using not only quantitative methods but also qualitative ones (e.g. performance levels for a service);

c) address applicable requirements;

d) be relevant to conformity of products and services and enhanced customer satisfaction; for example, specifying functionality or performance needs for a product such as On Time and In Full (OTIF), or defining a service level agreement;

e) be monitored and/or reviewed for progress being made in achieving the quality objective; this could be carried out through any suitable means, including progress reports, customer feedback or management reviews, etc.;

f) be communicated as necessary (see ISO 9001:2015[28], 7.4); the organization should communicate its quality objectives throughout the organization and to interested parties, as necessary; for example, through meetings to inform relevant persons of the quality objectives related to their activities, or notifying manufacturing persons about expected reductions of scrap, or specifying in writing to an outsourced service provider its quality objectives related to on-time delivery of service;

g) be updated as appropriate; potential or actual changes that can impact on the ability to achieve quality objectives need to be considered and action taken as necessary, to ensure new issues or requirements are addressed.

Quality objectives should be set and measured using suitable techniques, such as SMART (i.e. setting quality objectives that are Specific, Measurable, Achievable, Relevant and Time-bound), balanced score cards, or dashboards; quality objectives should be updated or added to as necessary, to reflect any changes implemented.

When setting quality objectives, the organization should also take into consideration factors such as its current capabilities and constraints, customer feedback and other market issues.

EXAMPLE At the service delivery/customer interface or at the production line, quality objectives can be very simple and direct, e.g.

— a transport organization running a bus service might set an objective for the percentage of buses that will run to the scheduled timetable within set limits;

— at a production location, the objective output per hour with maximum acceptable reject level can be set;

— in a hairdressing salon, for the times when all available staff are busy, one person can be assigned to greet new customers; the objective here might be that "customers entering the shop are to be welcomed within one minute and their requirements determined".

The organization needs to maintain documented information on quality objectives. Examples of where an organization can choose to maintain documented information include, but are not limited to, business plans, balanced score cards, dashboards, intranet and communication boards.

6.2.2 The intent of this subclause is to plan actions in order for an organization to achieve its quality objectives.

For ISO 9001:2015[28], 6.2.2, bullets a) to e), the organization should:

a) determine the actions that need to be implemented to achieve its quality objectives;

b) ensure sufficient resources are made available (see ISO 9001:2015[28], Clause 7);

c) determine who is responsible for achieving specific quality objectives (this can be a team or department rather than a single individual);

d) decide when an action will be completed;

e) decide how the results will be evaluated.

The evaluation of results (see ISO 9001:2015[28], 9.1.3) on achieving specified quality objectives can be part of management review, performance appraisals or done through other means such as project management with proposed completion dates, KPIs, or ongoing review or feedback meetings.

6.3 Planning of changes

The intent of this subclause is to determine the need for changes to the organization's quality management system in order to adapt to changes in its business environment, as well as to ensure that any proposed changes are planned, introduced and implemented in a controlled manner.

Properly planning a change can help to avoid negative consequences such as rework, or cancellation or postponement of a service; it can also result in positive consequences such as the reduction of nonconforming outputs, or reduced incidents of human error. The purpose of planning the change is to maintain the integrity of the quality management system and the organization's ability to continue to provide conforming products and services during the change. The organization should consider actions that could reduce the potential for negative impacts of the change, such as first conducting a trial of the change before full implementation, or determining actions to be taken when the change is not successfully implemented.

The application of risk-based thinking can be helpful in determining the actions necessary in planning changes to the quality management system. The organization should consider the availability of resources and necessary allocation or reallocation of responsibilities for any change. This could be done by assigning persons to a team to manage the change, or by delaying the change until the right resources are available.

The need for a change to the quality management system can be determined in many different ways, for example as part of management review, from audit results, reviews of nonconformities, complaints analysis, analysis of process performance, changes in context or from the changing needs of customers and other relevant interested parties.

The need for changes can result from, for example, the transfer of production lines from one site to another, changing process methods to improve trends in non-conforming outputs, using new information and communication technology (ICT) for a service or process, outsourcing important processes, persons in key roles leaving (either due to retirement or medical issues), or moving to online order handling.

The impact of such changes on the quality management system should be evaluated by the organization and the necessary actions taken to prevent undesired effects. This can range from the application of project management approaches to establishing performance and validation testing of new processes

and systems on a pilot basis before they are implemented. The level of planning and action required will vary depending on the potential consequence(s) of the change.

To help plan the change, examples of actions the organization can take include:

a) with the introduction of new software for order handling, the organization might plan performance tests and validation, and run both the old and new systems concurrently for a limited time to ensure the new system operates as intended before being fully adopted;

b) in deciding to establish a new office for service provision in a new geographic area, the organization might choose to apply formal project management techniques.

7 Support

7.1 Resources

7.1.1 General

The intent of this subclause is to ensure that the organization provides the resources necessary for the establishment, implementation, maintenance and continual improvement of the quality management system, and for its effective operation.

In determining the resources that need to be provided, the organization should consider the current capabilities of its internal resources (e.g. people, capability of equipment, organizational knowledge) and any constraints (e.g. budget, number of resources, schedule).

During the determination of resources, the organization can consider an analysis of costs versus benefits for the provision of these resources, using risk-based thinking. A decision should then be made on the resources needed, including those to be sourced externally, and the necessary actions taken to ensure the resources needed are provided; this applies to ISO 9001:2015[28], 7.1.1 to 7.1.6.

7.1.2 People

The intent of this subclause is to ensure that the organization has the right human resources that are needed for the operation and control of its processes and the effective implementation of the quality management system. Consideration should be given to the current work load and competence of relevant persons to carry out functions and roles in the quality management system (e.g. operational activities, audits, inspection, testing, complaint investigations).

In determining the persons needed, the organization should use risk-based thinking and consider the responsibilities and authorities that have been designated for specific processes.

An organization might decide to recruit extra persons or use an external provider, in which case the organization should consider such factors as the need for additional training, establishment of service level agreements, or audits of service providers to ensure the necessary performance is achieved. Full consideration should be given to competence requirements (see ISO 9001:2015[28], 7.2).

7.1.3 Infrastructure

The intent of the clause is to ensure that the organization has the facilities, equipment and services needed to consistently provide conforming products and services to its customers.

The actions of “determine”, “provide” and “maintain” relate to three different activities that might be performed by different processes or functions of an organization. For example, those responsible for a particular process might determine specific infrastructure requirements, the purchasing process will acquire and provide that infrastructure, and activities will need to be established to maintain it (such as equipment maintenance, housekeeping, or information technology updates, periodic testing of information and communication systems, or periodic inspections of facilities and equipment).

Infrastructure can have a critical effect on achieving conformity of products and services. The organization is required to:

a) determine the necessary infrastructure for the effective operation of its processes and to achieve its intended results;

b) provide and maintain the necessary infrastructure.

In determining the necessary infrastructure, the organization should consider what facilities, equipment, computer software, services and/or transportation, etc., is needed to provide conforming products and services. Infrastructure needs can vary depending on the type of products and services provided by the organization. For traditional manufacturing and assembly processes, infrastructure can include facilities for manufacturing, packaging, distribution, transportation and ICT systems.

In service organizations, infrastructure can involve IT systems or workspace; for example, in the delivery of health services or consultancy services, the internet systems for on-line purchasing or banking, or the corporate headquarters.

Other examples of infrastructure include:

— protective equipment to prevent contamination at a bottling company;

— appropriate air conditioning and clean room environment for a hospital;

— ICT for processing customer credit card transactions;

— resources to manage the noise level in a factory so the operators can hear process sounds necessary for process monitoring.

7.1.4 Environment for the operation of processes

The intent of this subclause is to ensure that the organization determines and provides the necessary environment for the operation of its processes, to facilitate provision of conforming products and services.

When determining the environment for the operation of the processes, inputs from interested parties should be considered as necessary. For example, a regulatory authority could have established specific requirements for cleanliness of the work environment in order to avoid contamination.

The requirements for the process environment can vary greatly depending on the type of product and service provided. In some cases the process environment only needs to address physical issues such as temperature, lighting, hygiene, airflow, noise, etc. In other circumstances physical issues such as cleanliness can be a critical factor, for example, in computer chip manufacturing which requires clean room environments.

In some cases, human factors can be critical in the process; therefore, they should be considered when determining the environment for the operation of the processes, for example by avoiding high workloads and stress (to prevent potential errors, burn-out, or bullying) for employees, and by providing information (e.g. on waiting times for service areas) for customers.

Other factors can also need consideration, such as social and psychological issues. Examples are: human factors such as encouraging a learning environment for a pre-school; holding a mediation service in suitable environment in order to avoid confrontation; allowing sufficient rest time to prevent accidents, for example, by limiting pilots' flying hours or limiting the driving hours for those involved in providing freight and distribution services.

It is not intended that you should implement a formal environmental management system or an occupational health and safety management system, to meet the requirements of ISO 9001:2015[28], 7.1.4, unless these are appropriate.

Once determined, the environment for the operation of processes should be suitably maintained and controlled as necessary.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The intent of this subclause is to ensure that the organization determines and provides suitable resources to ensure valid and reliable monitoring and measuring results, when evaluating the conformity of the organization's products and services.

The resources needed for monitoring and measuring vary greatly depending on the types of products and services provided by an organization and the processes established for the quality management system.

In some cases, a simple check or monitoring will be sufficient to determine the status. In other cases, a measurement will be needed and this could require measuring equipment that needs to be verified or calibrated, or both.

Monitoring implies critical observation, supervision and checks to determine the quantitative or qualitative status (or both) of an activity, a process, a product, or a service. It can be a simple check to ensure the correct quantity is there or that an order is complete; a gauge to indicate something is correct; by listening in to a conversation between a customer and a call-centre ("your call could be monitored for quality purposes"), or by asking questions during service provision, such as a waiter asking if the customer is satisfied with the food and service being provided.

Measurement considers the determination of a quantity, magnitude, or dimension, by using suitable measuring resources. This can include the use of calibrated or verified equipment that is traceable to national or international measurement standards. For services, it can include the use of known and validated models for service feedback, for example social service models.

The organization needs to consider how critical monitoring and measurement is in determining conformity of its products and services.

In determining the criticality of monitoring and measurements to ensure valid results, the organization should determine what needs to be monitored and/or measured for its processes, products and services. The organization should then determine the resources needed for this monitoring and measuring, ensuring its suitability for what is required.

Documented information should be available to demonstrate the fitness of purpose of the monitoring and measuring resources selected. This can include schedules outlining how often checks are needed to ensure valid results, or information demonstrating traceability to national standards or any alternative basis used.

In some cases, an expert can be required to evaluate if products and services are correctly provided, for example a chef in a restaurant, a social worker to evaluate foster care provision, or a medical professional for health care services. In some cases a tool needs to be developed to be used to confirm that requirements have been met, such as a rubric or marking scheme used to grade an examination.

7.1.5.2 Measurement traceability

The intent of this subclause is to ensure that the organization provides measurement traceability when it is a requirement or when the organization determines it to be necessary to have confidence in the validity of the measurement results.

If measuring equipment is used to verify conformity to requirements and to provide confidence in the validity of measurement results, the organization should consider how the measuring equipment is verified and/or calibrated, controlled, stored, used and maintained.

The status of calibration/verification should be identified (e.g. whether the measuring equipment has been calibrated/verified, and if so, to what extent and until when it can be used). This identification might be on the measuring equipment itself, on its container or by other administrative means such as the use of a unique identifier for the equipment that can be matched to a database. Measuring

equipment with adjustable features for calibration should be protected to prevent inadvertent change in calibration status. This can be done by a fastening or covering the adjustment section to prevent disruption with fingers or tools.

In situations where the calibration status might be affected due to vibration or shock, the equipment should be protected with methods such as a customized case or packaging.

Measurement systems can also include the combination of software and other devices, such as fuel pumps or signals to control process parameters. In these cases, the organization should consider the fitness for purpose of the full measurement system.

The establishment of calibration schedules and maintenance checks for measuring equipment should be considered based on the risks and criticality of the measurement in determining conformity of products and services.

If measuring equipment is found to be unfit for the intended purpose, the potential impact on compliance with measurement requirements should be reviewed and necessary actions taken. Actions can include checking a sample of the affected product to determine if it meets acceptance criteria.

The results of such a review can also indicate that no action is required or, alternatively, that a service needs to be performed again, products in stock need to be investigated, or relevant customers have to be informed, or even that a product recall is required. The level of action needed depends on the conformity of products and services.

7.1.6 Organizational knowledge

The intent of this subclause is to maintain knowledge determined by the organization as necessary for the operation of its processes and to achieve conformity of products and services, as well as to encourage the acquisition of necessary knowledge based on changing needs and trends.

Organizational knowledge is the specific knowledge of the organization coming either from its collective experience or from the individual experience of its persons. This knowledge is or can be used to achieve the organization's quality objectives or its intended results.

The organization should consider how to determine and manage the organizational knowledge required to meet its present and future needs. Persons of the organization and their experience are the foundation of organizational knowledge. Capturing and sharing such experience and knowledge can generate synergies leading to the creation of new or updated organizational knowledge.

A complex organization could choose to implement a formal knowledge management system, whereas less complex organizations might choose to use simpler methods, such as by maintaining logbooks on design decisions or on the properties and performance of chemical compounds that were developed and tested.

In determining, maintaining and making available organizational knowledge, the organization can consider:

a) learning from failures, near miss situations and successes;

b) gathering knowledge from customers, external providers and partners;

c) capturing knowledge that exists within the organization, e.g. through mentoring, succession planning;

d) benchmarking;

e) an intranet, libraries, awareness sessions, newsletters, etc.

7.2 Competence

The intent of this subclause is to determine the required competence for the jobs or activities in the organization that can affect conformity of products and services or customer satisfaction, and to ensure that the persons holding those jobs or carrying out those activities (e.g. managers, existing employees, temporary employees, sub-contractors, outsourced persons) are competent to perform them.

The competence of persons can be based on their education, training, and experience. Those who are able to demonstrate their competence are sometimes referred to as being qualified.

The organization should determine competence requirements by either an activity or job position/role. Certain tasks can require a specific level of competence before they can be performed properly or safely (e.g. internal quality auditing, welding, or non-destructive testing). It might be necessary for persons to be qualified for some tasks (e.g. forklift or truck driving, or surveying). Competence requirements can be determined by different methods, such as through defining job descriptions, or by carrying out job evaluation exercises, when jobs are analysed.

The competence of a person should be confirmed by reviewing whether he or she has the appropriate education, training, or experience. This might be done through job interviews, reviewing resumes, observation, documented information of training or diplomas.

When a person from the organization does not meet or no longer meets the competence requirements, then actions should be taken; such actions can include, but are not limited to, mentoring the employee, providing training, simplifying the process so that the person can carry it out successfully, or reassigning the employee to another position.

The organization should also evaluate the effectiveness of any actions taken. For example, the organization might ask persons who have received training whether they consider themselves to have achieved the competence necessary to do their work. This can also be evaluated by different means, including direct observation of his/her performance or by examining the results of tasks and projects.

When a person doing work under the organization's control is from an external provider, additional controls and monitoring could be required, such as audits of externally provided processes, inspection of products and services, or establishing contract and service level agreements specifying competence requirements. The organization is responsible for determining the action to be taken, which will vary depending on how critical competence is in ensuring conformity to requirements.

The organization should retain appropriate documented information that provides evidence of an employee's competence, e.g. diplomas, licenses, resumes, and from completion of training, and performance reviews.

Where employees have a formal certified education (e.g. a university degree) such certification can be used to demonstrate that they have acquired part, or all, of the knowledge required to carry out their work, but not necessarily that they are able to apply that knowledge. Other forms of more vocational training (e.g. nursing, or an apprenticeship as a mechanic) can also include the ability to apply knowledge and skills.

7.3 Awareness

The intent of this subclause is to ensure that relevant persons doing work under the organization's control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the quality management system and the implications of not conforming with quality management system requirements.

Awareness is attained when persons understand their responsibilities and authorities and how their actions contribute to the achievement of the organization's quality objectives. Many organizations create awareness through communication (see ISO 9001:2015[28], 7.4).

Persons doing work under the organization's control can demonstrate their awareness in day-to-day activities by distinguishing between what is acceptable and what is not, and by taking appropriate

action when processes, products and services do not meet agreed specifications. These persons should understand what the implications are if there are nonconformities in the quality management system (e.g. rework, scrap, customer dissatisfaction, legal implications). Depending on the nature of the work that the persons perform, the actions for creating awareness can vary.

The organization should ensure that the persons of the organization understand how they contribute to the effectiveness of the quality management system, by performing work processes that achieve conforming outputs, which in turn helps customer satisfaction.

The organization can create awareness in many ways, such as:

a) clarifying what is expected (e.g. visual tools such as pictures of acceptable and unacceptable products and services);

b) communicating clear requirements for products and services;

c) designing processes to clearly segregate nonconforming outputs;

d) communicating clearly how to handle complaints and the internal escalation steps in the case of nonconforming outputs.

Communication of all kinds is important to ensure awareness and can include regular review meetings, customer and external provider meetings, gathering feedback and ensuring this feedback is made known to relevant persons.

7.4 Communication

The intent of this subclause is to ensure that the organization establishes the internal and external communications that are needed and which are relevant to the quality management system.

The organization should determine on what it needs to communicate. This might be different for internal and external parties. For example, the organization could communicate about the status of the quality management system with persons of the organization, but communicate with external providers about new terms and conditions on purchase orders.

The organization should determine those relevant internal and external parties with whom they need to communicate, to ensure the effective operation of the quality management system. This can include relevant persons within the organization at all levels and relevant interested parties (such as customers, external providers used to source products and services, or regulatory bodies).

Different communication methods are often required for different situations. More formal communication, such as reports, specifications, invoices or service level agreements, might be required for external relevant interested parties. For internal communication, methods such as daily contact, regular department meetings, briefing sessions, email or an intranet may be used. More formal methods such as written reports or job specifications could also be required for internal communication, depending on the nature of the information and how critical the issues are that need to be communicated.

The organization should also determine who will communicate. This will depend on the nature of the communication and with whom the organization is communicating. For example, top management might communicate with persons of the organization while the owner of the purchasing process might communicate with external providers.

To be effective, the organization's communication processes should provide it and its persons with the ability to:

— transmit and receive information quickly and to act on it;

— build trust amongst each other;

— transmit the importance of customer satisfaction, process performance, etc.;

— identify opportunities for improvement.

7.5 Documented information

7.5.1 General

The intent of this subclause is to ensure that the organization controls the documented information needed for conformity to ISO 9001, as well as the documented information that it has determined is needed for the effectiveness of its quality management system (see ISO 9001:2015, 4.4.2[28]).

When ISO 9001 refers to "maintain documented information", this means ensuring that information is kept up-to-date, e.g. the information contained in documented procedures, manuals, forms and check-lists, information that could be stored in the cloud and downloaded to a smartphone or other electronic device, and other documented information (such as the quality policy and quality objectives).

When ISO 9001 refers to "retain documented information", this means ensuring that information that is used to provide evidence about whether or not a requirement has been fulfilled is protected against any deterioration or unauthorized change (that should not occur, unless an agreed correction has to be made).

In general, ISO 9001 is not prescriptive in terms of the extent of documented information needed. This will vary from organization to organization depending on the size and complexity of the operations and processes; customer, statutory and regulatory requirements; and the competence of the persons involved. For example, documented information needed for a small bakery will be simpler and less extensive than that needed by an automotive parts manufacturer which has very specific customer (statutory and regulatory) requirements, including documented information of external origin, to be incorporated into the system.

7.5.2 Creating and updating

The intent of this subclause is to ensure that, when the organization creates and updates documented information, the appropriate identification, format and media is used, and it is reviewed and approved.

Documented information should include an identification and description. There are many methods for this, such as defining a title, date, author, or reference number (or a combination of two or more of these methods) that an organization can use to determine information and its status.

The organization should establish the format for the documented information. The organization can use hard copy, electronic or both to provide documented information. Consideration should also be given to what software version will be used since it is possible that not all users will have access to the same version. Some organizations might need to consider providing the documented information in more than one language, based on the culture of the organization.

The organization should have established methods for the review and approval of its documented information, e.g. having an identified person with the authority to approve the document information.

7.5.3 Control of documented information

7.5.3.1 The intent of this subclause is to ensure that documented information is available in a suitable medium whenever needed, and that it is adequately protected.

Having decided on what documented information is needed for the quality management system, the organization should ensure it is available for all relevant areas, departments, process owners etc. Consideration should also be given to providing relevant documented information to relevant external interested parties when products and services are sourced externally. The documented information should also be in a form that is suitable for intended use, for example a written service level agreement for an external service provider, or process parameter information in electronic format that can be downloaded at the process interface.

The organization should consider the level of control needed to ensure documented information is suitably controlled, considering the media it is in. Control includes availability, distribution and protection, for example from loss of data, confidentiality, improper use and unintended changes. The organization should ensure the necessary controls are in place as part of the system for documented information and communication and that it is protected from such loss, improper use or unintended change. This can be done in many ways, including electronic systems with read-only access and specified permissions in order to access different levels, password protection or identification (ID) entry. The level of control can vary depending on where the documented information is to be made available; for example, increased access restrictions for external parties. Information security issues and data back-up should also be taken into consideration.

7.5.3.2 The intent of this subclause is to ensure that the control of documented information addresses distribution, access, retrieval and use, storage and preservation, control of changes, retention and disposition. This also applies to documented information of external origin where they are determined by the organization to be necessary for the planning and operation of the quality management system. Distribution of documented information can be controlled by different methods.

Having established a system for controlling distribution and access to documented information, the organization should then consider how it is stored, maintained and disposed of as necessary over time.

Documented information can change and develop as an organization improves its processes and its quality management system.

There is also a need to consider how historical documented information is maintained, stored and retrieved as necessary for subsequent use.

Consideration should be given to version control, where the organization determines some means of identifying current from obsolete documented information and establishes controls to ensure that only current documented information is used.

The storage of obsolete documented information can be important. The documented information should be maintained in an appropriate medium to ensure its preservation and legibility, for example for the investigation of complaints many years after production that can require historical production data, or for organizational knowledge management purposes. The retention time for documented information could be a statutory or regulatory requirement, a contractual requirement, or can be determined by the organization (depending on the lifetime of its products and services). For the disposal of obsolete and unnecessary documented information the organization should give consideration to the control of sensitive data (e.g. personal or confidential information) during the disposal process.

Where documented information of external origin is determined by the organization as being necessary for the planning and operation of the quality management system, it should be identified appropriately and controlled in line with other documented information. This can include documented information from a customer or external provider such as drawings, specified test methods, sampling plans, standards or calibration reports. Particular care should be given to the control of sensitive data.

When documented information is retained as evidence of conformity, it should be protected from unintended alterations. An organization should allow only controlled access to such information, e.g. authorized access for relevant persons working on behalf of the organization or restricted electronic access such as “read only”, as appropriate.

8 Operation

8.1 Operational planning and control

The intent of this subclause is to ensure that the organization plans, implements and controls the processes that are necessary for its production and service provision, including any externally provided processes (see ISO 9001:2015[28], 8.4).

The risks and opportunities and quality objectives determined during planning (see ISO 9001:2015[28], Clause 6), including potential changes, are key inputs for consideration in the planning and control of the operations and establishing criteria for processes and acceptance of products and services.

Based on the nature and complexity of the processes for production and service provision, the organization will need to determine what resources are needed and if the current resources are sufficient.

Effective controls are needed to:

a) confirm that the criteria are met;

b) ensure that the intended outputs are delivered;

c) determine where improvement is needed.

The criteria and their associated supporting documented information are the output of this planning.

The output of this planning will need to be used as inputs to operations within the organization. It might also need to be used by customers or external providers. It should be kept in suitable formats and media for those who need to use it.

When planning its operations and control criteria the organization should consider both planned and potential unintended changes, and how these changes can affect its operations.

When planning the processes to provide products and services, outsourced processes need to be under the organization's control if they are relevant to its quality management system. The control has to be ensured by applying the requirements for the control of externally provided processes, products and services (see ISO 9001:2015[28], 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

The intent of this subclause is to ensure there is clear communication between the organization and its customer when determining requirements for the products and services to be provided.

For ISO 9001:2015[28], 8.2.1, bullets a) to e), the organization should:

a) communicate details of the product or service to be provided so that the customer understands what is being offered; this information can be communicated through meetings, leaflets, websites, by telephone or any other appropriate means;

b) make clear:

   — how the customer can contact the organization to ask questions or order products or services;

   — how the organization will inform the customer of any related changes;

c) establish appropriate ways to gain information from the customer related to questions, concerns, complaints, positive and negative feedback; methods include but are not limited to: direct email or phone calls, online surveys, customer support channels, face-to-face meetings;

d) ensure that the customer is informed of how the organization handles and controls customer property, where appropriate;

e) ensure that it is proactive in communicating with the customer about possible contingency actions that can be taken, if the need occurs, to avoid having a detrimental effect on meeting customer requirements; this could include situations such as natural disasters, weather, labour disputes, shortfall of raw materials or of backup external providers.

This communication enables the customer to understand what the organization can or intends to provide and enables the organization to understand or confirm the needs and expectations of the customer.

8.2.2 Determining the requirements for products and services

The intent of this subclause is to ensure that the organization determines the requirements for its products and services. These requirements can be determined by considering:

a) the purpose of the product or service;

b) customer needs and expectations;

c) relevant statutory and regulatory requirements;

d) those requirements considered necessary by the organization (e.g. the numbering of parts, or the naming of files, for traceability within the organization).

The organization needs to ensure it meets the claims for the products and services it offers. A claim is a statement by the organization about its products and services and their features and characteristics that it can provide to customers. For example an internet service provider (ISP) might make claims about download speeds on its website; a manufacturer of laptop computers might make claims about battery life in a brochure; a car manufacturer makes claims about fuel economy in an advertisement; or an insurance company says it provides a 24 hour claims service.

The organization should consider factors such as:

— available resources;

— capability;

— capacity;

— delivery times.

ISO 10001 gives advice about codes of conduct, which is related to the making of claims.

8.2.3 Review of the requirements for products and services

8.2.3.1 The intent of this subclause is to ensure that the organization reviews the commitments it makes to a customer and has the ability to meet these commitments. The review enables the organization to reduce the risk of issues arising during operations and post-delivery.

For ISO 9001:2015[28], 8.2.3.1, bullets a) to e), the organization should review:

a) the need for delivery and post-delivery actions such as transportation, user training, on-site installation, warranties, repairs, customer support;

b) whether implied requirements can be met, i.e. the product or service should be able to meet the customer's expectations (e.g. a hotel room is expected to be clean and provide basic facilities and its staff are expected to be polite and helpful; or bottled water should be safe to drink);

c) additional requirements which the organization chooses to meet to exceed customer expectations, enhance customer satisfaction or to comply with internal policies;

d) whether applicable statutory and regulatory requirements have been considered and addressed;

e) if changes have been made to the contract or order.

If there is a difference between previously defined requirements and those stated in the contract or order, the organization will need to communicate with the customer and resolve these differences.

If a customer does not provide a documented statement of their requirements, for example when ordering by telephone or by a verbal instruction, the requirements will need to be confirmed with the customer before the product or service is provided (e.g. in a restaurant an order for food can be repeated back to the customer).

8.2.3.2 The intent of this subclause is to ensure that documented information is retained to demonstrate the final agreement with the customer, including any corrections or changes, and show that the requirements can be met.

For ISO 9001:2015[28], 8.2.3.2, bullets a) to b):

a) the results of the review can be retained in any suitable media, e.g. a restaurant could keep a written or electronic order detailing what the customer wants to eat; a company could choose to retain selected email communications with the customer, while a complex construction project could keep a detailed report of the feasibility analysis;

b) if the review identifies an additional or changed requirement, the documented information should be updated or added to, to ensure the new requirement is captured (e.g. an email conversation changing an order or resolving a misunderstanding should be retained).

This documented information can provide a basis for similar future agreements with new or existing customers.

8.2.4 Changes to requirements for products and services

The intent of this subclause is to ensure that relevant persons (both inside and outside the organization) are aware of any changes to the requirements for products and services. The organization should choose a suitable method of communication and retain appropriate documented information, such as the communication email, meeting minutes or amended order.

8.3 Design and development of products and services

8.3.1 General

The intent of this subclause is to ensure that the organization establishes, implements, and maintains a design and development process, in order to ensure that its products and services meet requirements, and which defines the characteristics of the products and services. The organization should consider the context of the organization, including the relevant interested parties, in determining the scope of the quality management system (see ISO 9001:2015[28], 4.3), as this scope determines the application of the requirements of ISO 9001:2015[28], 8.3.

Some organizations could need to consider all of the design and development requirements while other organizations will only need to consider some of the requirements, such as for design and development changes or for communicating with the customer.

For example, an organization manufacturing its own range of bicycles needs to consider the design and development requirements for a new or modified product. An organization manufacturing a product precisely to a customer's design needs to consider design and development requirements only if the customer makes modification to that design or if there are communications about a product change.

Similarly a coffee-shop operating under franchise could need to meet less design and development requirements than an independent coffee shop that makes its own decisions about products, décor and marketing.

In some cases, an organization could decide to apply the requirements for design and development to its operational processes, either based on the scope of the quality management system, customer or statutory and regulatory requirements, or best business practices.

EXAMPLE Examples of where design and development is needed include:

— a tailor who receives a request from a customer to add a piece of fabric to a previous dress or suit;

— a small shop which has a specification for a pneumatic clutch, and a customer requires a change on the fit that will require a customization of the clutch;

— a financial advisory organization that designs and develops the services it offers to its clients in relation to managing their stock portfolios;

— an educational organization which designs and develops its curricula.

8.3.2 Design and development planning

The intent of this subclause is to ensure that the organization carries out design and development planning to determine its necessary design and development activities and tasks. This planning should include consideration of the actions determined to be necessary (in ISO 9001:2015[28], Clause 6 and 8.1) that can have an effect on the performance of the planned activities, the resource needs, as well as a clear definition of roles and responsibilities.

The requirements in this subclause provide a set of key elements to be considered during the design and development planning. For ISO 9001:2015[28], 8.3.2, bullets a) to j), these include:

a) the complexity of the products and services (e.g. repeat design, new design, purpose of product and service, physical characteristics such as the intended duration and extent of a service) and factors such as delivery requirements;

b) necessary stages, including applicable design and development review (e.g. basic design, detailed design) as well as verification (e.g. are all dimensions adequately specified on a technical drawing) and validation (e.g. trial production or service tests);

c) the verification activities needed to ensure that outputs meet the input requirements and validation activities needed to ensure that the resulting products and services meet the requirements for the specified application or intended use;

d) who is going to do it, i.e. determining the necessary responsibilities and authorities involved in the design and development process;

e) the internal and external resources needed (e.g. organizational knowledge, equipment, technology, competence, support from customers or external providers, temporary workers, codes or standards providing technical information);

f) communications between those involved in the design and development process, considering the number of persons involved and the most effective ways of sharing information, such as meetings, telecommunications, minutes;

g) the potential involvement of customers and users in the design and development activities (e.g. on-site monitoring by a customer, customer testing, customer research, or consumer experience);

h) what is needed in order for persons in the organization to provide the product or deliver the service (e.g. drawings, controls, raw materials, acceptance criteria);

i) expected levels of control determined by customers or other interested parties on the process (e.g. safety checks for medical devices or aircraft); where no explicit controls are determined by the customer or end user, the organization should determine what controls are necessary, considering the nature of the products and services;

j) the documented information needed to demonstrate if design and development requirements have been met and the process has been carried out appropriately at review, verification and validation stages; such as project plans, meeting minutes, completion of action items, test reports, drawings, work instructions, or process flow diagrams.

8.3.3 Design and development inputs

The intent of this subclause is to ensure that the organization determines the inputs for design and development projects as one of its activities during design and development planning. These inputs need to be unambiguous, complete and consistent with the requirements that define the characteristics of the product or service. For ISO 9001:2015[28], 8.3.3, bullets a) to e), the organization should consider:

a) the functional and performance requirements determined by customers, market needs or the organization; for example, the needed life cycle for a piece of equipment, a lamp that provides a certain amount of lighting, or a service being provided in a certain amount of time, a machine that can be operated in a safe manner, traffic flow on roadways;

b) information from previous similar design and development activities such as project files, drawings, specifications, or lessons learned, which can enhance effectiveness and enable the organization to build on good practices or avoid mistakes;

c) statutory and regulatory requirements that relate directly to the product or service (e.g. safety regulations, food hygiene laws) or the provision of that product or service (e.g. handling of chemicals that are part of the final product; transportation or other delivery mechanisms; wearing of gloves while providing a health service; hygiene requirements for a restaurant);

d) standards or codes of practice that the organization has committed itself to (e.g. industry codes, or health and safety standards);

e) the potential consequences of failure due to the nature of the products and services; such failures can range from the potentially fatal (e.g. at an event there is poor planning of road traffic safety, which can lead to accidents) to issues which result in loss of customer satisfaction (e.g. unstable inks in fabrics, leading to colour fading or running).

The applicable inputs for the design and development should be retained as documented information. These inputs could be a reference to a specific code or specification listed in the project planning.

Where input requirements conflict, or are difficult to address or achieve, the organization should implement activities to resolve the issues.

8.3.4 Design and development controls

The intent of this subclause is to ensure that once the inputs have been determined, the design and development activities and controls are implemented in accordance with the planning, to ensure the process is effective.

Review, verification and validation activities are essential for controlling the design and development process and need to be implemented effectively. It is possible for review, verification and validation to be completed as a single process or as separate activities. For ISO 9001:2015, 8.3.4[28], bullets a) to f), the organization should ensure:

a) that all persons involved in design and development activities are aware of, and fully understand, the customer or end user requirements and intended final outputs; deviations from these requirements, for example in planning to enhance product performance, need to be considered against factors such as cost and ease of use;

b) the reviews of the design and development planning stages and the output of the stage are in place to confirm they meet input requirements, determine problems and develop solutions; persons who are not involved in the specific stage of the design and development process can be involved in its reviews, including those involved in producing the product or service and where relevant customers, end-users and external providers; for differing levels of complexity:

   — a complex design might be reviewed in a formal meeting, and the minutes of such a meeting would constitute the record;

— a review for a simple design could be less formal, and the record might consist of a notation on the plan that the review has been carried out, signed off by the reviewer and dated;

c) verification is carried out to ensure that all requirements identified at the beginning of the design and development process are met; for larger projects, the process can be divided into key stages with required verification carried out at the end of the stage; verification activities can include:

— performing alternative calculations;

— comparing the new design with a similar proven design;

— undertaking tests and demonstrations;

— checking the design stage documented information before release;

d) validation is carried out to ensure that the final product or service will meet customer or end-user needs for a specific or intended use; examples of validation activities can include:

— marketing trials;

— operational testing;

— simulations and testing under intended user conditions;

— partial simulations or tests (e.g. to simulate a building's ability to withstand earthquakes);

— customer or end-user tests which provide feedback;

e) that if review, verification and validation activities reveal problems, actions to resolve these should be determined; evaluation of the effectiveness of these actions should be part of the next review;

f) that documented information of the review, verification and validation activities is retained as evidence that the design and development activities were carried out as planned; examples can include meeting minutes, inspection and test reports, and customer approvals.

8.3.5 Design and development outputs

The intent of this subclause is to ensure that the design and development outputs give the necessary information for all the processes needed to provide the intended products and services (including purchasing, production, and post-delivery activities); they should also be clear enough in order to ensure that those involved understand what actions need to be taken and in what sequence.

The design and development outputs will vary depending on the nature of the design and development process and the requirements for the products and services. The design and development outputs will be key inputs for the production and service provision processes (see ISO 9001:2015[28], 8.5).

For ISO 9001:2015[28], 8.3.5, bullets a) to d), these outputs should:

a) be consistent with the input requirements defined in accordance with ISO 9001:2015, 8.3.3[28];

b) be sufficient to ensure that all subsequent processes needed to provide the products and services can be carried out, taking into consideration who will use the output and in what circumstances;

c) provide clear information about what is required in relation to monitoring and measuring, including details of any acceptance criteria for processes, products and services that are externally provided, and the release of the products and services;

d) give essential information about product and service characteristics, to ensure the products can be produced or a service provided in a safe and suitable way, as well as detailing how the product or service is to be used (e.g. instructions for the use of a medicine, for storage of food, or how to clean a product).

In some cases, the design output can be the actual product of the organization, for example this can occur in the activities of architects, design engineers or graphic artists.

Design outputs should be retained as documented information, including but not limited to:

— drawings, product specifications (including preservation details), material specifications, test requirements, quality plans, control plans;

— process specifications, details of necessary production equipment;

— construction plans and technical calculations (e.g. strength, earthquake-resistance);

— menus, recipes, cooking methods, service manuals;

— a fashion design for clothing defined by sketches and a specification relating to the materials to be used;

— a graphics art design giving the form of a particular layout to be used in a publication;

— an advertising agency design in the form of a plan for the marketing campaign.

8.3.6 Design and development changes

The intent of this subclause is for the organization to determine, review and control changes made during or subsequent to the design and development process. The organization should consider as part of the design and development process how interactions with other processes or interested parties (e.g. customers or external providers) will be implemented and consider these when determining design and development changes.

Changes can arise from any activity within the quality management system and at any stage, including, but not limited to:

a) during the implementation of the design and development process;

b) after the release and approval of the design and development outputs;

c) as a result of monitoring customer satisfaction and the performance of external providers.

Documented information to be retained relating to changes in design and development can include the results of evaluation of the effect of changes on constituent parts or on a product or service already delivered to prevent adverse impacts. Review, verification and validation processes can often result in documented information detailing design and development changes. Documented information can also detail actions taken for affected subsequent processes (e.g. purchasing, production, provision of product or service) and how these are communicated.

The documented information should indicate who authorized the change. In some cases, this authorization is required from the customer or a regulatory body. The documented information can include an approved change order or an electronic sign-off of the change.

8.4 Control of externally provided processes, products and services

8.4.1 General

The intent of this subclause is to control processes, products and services that are provided by an external provider. External providers could include the organization's corporate headquarters, associate companies, suppliers, or someone to whom the organization has outsourced a process.

The organization is responsible for ensuring that externally provided processes, products and services conform to requirements (e.g. through incoming goods inspection, or surveillance of an outsourced service provider).

The organization should determine:

a) which internal processes interact with externally provided processes and the effect this provision has on operational performance;

b) which externally provided materials, components or services form part of the final product or service, or are critical for product or service provision;

c) the requirements and specific controls to be applied for external provision, depending on the effect they can have on the organization's operation and performance.

For example, the organization might require that:

— a raw material complies with a technical specification, to be verified through inspection or tests;

— maintenance activities provided by a partner company be carried out by persons with determined competence using specified safety equipment;

— an associate company (such as a sister plant that provides component parts for assembly) conducts verifications.

The organization needs to determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers. Implementation of such a process enables an organization to have a clear understanding of the current capacities of external providers, determine gaps in what is needed, and determine solutions to resolve these issues.

In situations where a parent company or customer mandates the use of a specific external provider, this could be the criterion that is established; however, the monitoring of performance for these types of external providers is still required.

8.4.2 Type and extent of control

The intent of this subclause is to establish the controls for external providers, in order for the organization to have confidence that the products and services to be provided will meet requirements.

The type and extent of control is based on what the potential impact that the externally provided process, product or service can have on the organization's ability to consistently deliver conforming products and services.

EXAMPLE In a printing organization, the paper quality could be critical. However, a travel agency might use normal, commercial stationery without the need for any quality related purchasing controls. The printing organization needs to monitor the performance of its paper providers very closely to ensure that the quality of its printed products remains at the expected level.

The organization should determine which controls are to be implemented by or for an external provider. The intent of these controls is to ensure that product or service provision will be carried out according to planned arrangements and that the product or service will conform to requirements.

The organization needs to ensure that processes provided by an external provider that is within the control of the organization's quality management system meet the applicable requirements of ISO 9001.

Examples of controls, include, but are not limited to:

a) the qualification of the persons taking the calls and the set-up of the information and communication system at the beginning of a shift, for an outsourced call centre;

b) an incoming inspection carried out by a qualified inspector, or a test carried out on a sample at the organization's laboratory, for a provided product;

c) a checklist used when verifying that all the planned activities were carried out for a bathroom cleaning service at a hotel or an office.

Verification activities that could be considered include, but are not limited to:

— receiving inspections (e.g. the inspection of office supplies might be simply a verification that the quantity ordered was delivered, where a delivery docket, signed by an employee, might involve all the documented information that is required);

— reviewing certificates of analysis;

— second party audits;

— tests (e.g. an organization may choose to inspect a sample lot or do some form of testing to verify conformance to requirements; alternatively, it might be equally effective and more efficient to review certificates of analysis or test results submitted by the external provider);

— evaluations of statistical data;

— evaluating performance indicators.

8.4.3 Information for external providers

The intent of this subclause is to ensure that the organization clearly communicates to external providers the requirements and controls it needs for externally provided processes, services or products, in order to avoid a negative effect on its operations or on customer satisfaction.

The organization should ensure its requirements are complete, clear and address any potential sources of ambiguity or confusion; both parties should agree to what is required. It is essential that all relevant details are clearly stated at the time of ordering; these can include, for example, drawings, catalogue or model numbers, response times, and the required delivery date and place.

The information to be submitted to the external provider (e.g. a written purchase order) should be checked prior to issue. In a small organization, it will probably be the person who does the buying who will do the checking for adequacy. This could simply involve reading and confirming the order over the telephone.

The purchasing information should provide details related to any methods, processes, and equipment that should be used, e.g. certain welding techniques, the use of specific calibrated equipment, or employee uniforms. Other factors that need to be clearly stated could relate to, for example, packaging, labelling, certificates of analysis, or test results. While it is essential to fully describe what is needed, unnecessary detail can lead to misunderstanding and incorrect provision.

The information should specify any competence requirements needed for persons from the external provider, such as a certified welder, or a qualified lawyer.

Requirements for how the external provider is to communicate with the organization should be included, such as a planned set of meetings to review progress, or identifying who in the organization will be their primary point of contact.

The performance of external providers needs to be monitored. The type and frequency of the monitoring that the organization will use should be included in the information. This could specify the level of performance that the external provider has to meet, or provide information relating to how the results of the organization's performance evaluations will be communicated.

At times, the organization or its customer could need to perform verification or validation at the premises of the external provider. This could be due to the size of the product, nature of the service, or due to time constraints for delivery.

EXAMPLE An interior decorator could need to visit a manufacturer to view curtain fabrics that have been ordered, or employees could need to be monitored while they are being trained at a training facility.

In these cases, the organization should provide information about such arrangements, such as the timing for the verification and validation and any other provisions (such as office space, administrative support or testing facilities) required from the external provider.

8.5 Production and service provision

8.5.1 Control of production and service provision

The intent of this subclause is for the organization to establish the controls for providing products and delivering services that ensure that the intended results are achieved, by reducing the potential for nonconforming outputs.

The organization should set conditions to control product and service provision to ensure that the criteria determined in ISO 9001:2015[28], 8.1 are met.

The organization should consider the full cycle of production and service provision when determining what needs to be controlled, including requirements for post-delivery activities (such as installations, guarantees or complaints handling). For ISO 9001:2015[28], 8.5.1, bullets a) to h), all applicable aspects of the following should be considered:

a) the availability of documented information defining the characteristics of the products to be produced, the services to be provided, or the activities to be performed; the organization should provide documented information that is understandable to those who are involved in the activity or process, such as specifications or work instructions, and which helps to ensure that the products and services conform to specified requirements (ISO 9001 does not require the organization to produce documented information containing all the details which a competent operator should know);

   EXAMPLE 1 It is not usually necessary to describe to a trained forklift driver how to operate a forklift; however, work instructions might be needed to detail stacking arrangements, handling restrictions and routine maintenance.

b) any necessary monitoring and measuring resources; this could be identified measuring equipment that has been calibrated to make a certain measurement or a prescribed method to be used in delivering a service;

c) any monitoring and measurement activities needed to ensure that outputs meet the requirements for the product or service, such as inspection of product at determined stages, or the monitoring of customer service calls;

d) any necessary criteria for infrastructure (see ISO 9001:2015[28], 7.1.3) or the processes environment (see ISO 9001:2015[28], 7.1.4);

e) the need to ensure the competence of persons to do the work (see ISO 9001:2015[28], 7.2), including consideration of any necessary qualifications, such as those for non-destructive inspectors, or medical practitioner licenses;

f) ensuring that processes where the outputs cannot be verified by subsequent monitoring or measurement are validated (validation is the confirmation, through the provision of objective evidence, that requirements for a specific intended use or application have been met); examples of processes where the resulting outputs cannot be verified through subsequent inspection can include certain kinds of surface treatments, emergency responses, or contingency actions such as landing a plane on water;

g) the organization should take actions to prevent human error such as: limiting excessive working hours, putting in place appropriate measures to promote a suitable working environment, providing appropriate training and instructions, automating processes, requiring double electronic entry of critical information, making available devices to avoid incorrect tooling, avoiding distractions for persons (such as personal electronic devices), job rotation, requiring completion of information before submission;

h) the implementation of controls for release, delivery, and post-delivery activities; this will vary depending on the organization but typically include actions such as final inspection, maintenance or warranty.

EXAMPLE 2 Spot welding equipment will only continue to produce good welds if there is periodic maintenance of the condition of the electrodes.

8.5.2 Identification and traceability

The intent of this subclause is to ensure that the organization uses identification and traceability in order for it to be able to determine the processes, products or services that could be affected by potential nonconforming outputs throughout the production and service delivery process. Different methods of identifying outputs should be used by organizations depending on the nature of the product or service. In selecting a method of identification the organization should consider:

a) why the output needs to be identified, such as statutory and regulatory requirements (e.g. in the aerospace or food industries);

b) at which stage or stages in a process identification is made and how this is done.

The reasons for having identification and traceability vary.

EXAMPLE 1 In the clothing industry, materials from the same dye lot are usually processed as a batch to avoid colour mismatch problems; in a courier service, there is a need to keep track of items being picked up and delivered to maintain delivery commitments and schedules; in manufacturing, there could be a need to ensure that all raw materials are lead-free or that components can be traced back to origin.

In some industries, identification and traceability are specified requirements either by regulation or contract.

EXAMPLE 2 In pressure vessel manufacturing, it is common for the identification of a given material to be recorded and traced through all manufacturing stages, so that the end component can be traced to the original material.

The identification methods will vary depending on the nature of the outputs, e.g.

— a code, title or combination of those can be used to identify a contract or purchase order;

— a part number or permanent marking or label on a physical part of a product;

— a visible, physical, sign indicating provision of a service, such as cleaning within a hotel;

— a system of file naming for electronic documented information.

Where there is a requirement to be able to trace outputs, the organization should ensure that relevant documented information about the identified process output is retained and available. This might be necessary, for example in the case of a product recall; when measuring equipment is found to be out of calibration (see ISO 9001:2015[28], 7.1.5.2); in the investigation of process, product and service nonconformities, or as a result of statutory or regulatory requirements (who administered a certain controlled drug in a hospital, for example).

ISO 10007[8] gives further advice about configuration management.

8.5.3 Property belonging to customers or external providers

The intent of this subclause is to ensure that property that does not belong to the organization, but that is under the organization's control, is protected.

Customer property is property that is incorporated into or used for the production of products or the provision of a service. External provider property is property that is provided to the organization to be used for a purpose (e.g. equipment that is used for packaging or personal data).

Property can be tangible or intangible (e.g. material, tools, customer premises, intellectual property or personal data).

EXAMPLE 1 Examples of where a customer could provide material, equipment, knowledge or data to be used in producing products or delivering services include:

— instruments provided for measurement purposes;

— a motor vehicle left for service or repair;

— components for placement on a printed circuit board;

— special packaging for the finished product;

— a domestic appliance (e.g. a washing machine) left for repair;

— financial and personal data provided to a credit card company or for shopping on the internet.

The actions an organization should take to protect it will depend on the type of property.

The owner of the property should be clearly identified and made known within the organization, as applicable. This could be by identification on the product or by keeping the customer property in a segregated area, or by limiting access to intellectual property.

EXAMPLE 2 Examples of measures that you might adopt to protect your customer intellectual properties or personal data include:

— a specific location or file to store customer's intellectual data, including product drawings, patent information, performance and sales figures;

— password protection of computer files;

— a procedure requiring customer specifications and data be deleted at the end of a project;

— limiting access to information to specific and trained individuals.

Verification of the property when the organization takes control of it is important (e.g. state or physical condition, accuracy of personal data). This verification will vary based on the requirements of customers or external providers.

The intent of requiring documented information in this subclause is to ensure relevant information can be used to ensure that the customer or external provider is accurately informed if property is lost, damaged, or otherwise found to be unsuitable of use or incapable of being used.

8.5.4 Preservation

The intent of this subclause is to ensure that outputs and products and services are preserved at all stages during production and service provision.

The organization should determine those outputs which can deteriorate or degrade and affect conformity of the product or service, and implement appropriate preservation methods.

For example:

a) in the service industry, the need for preservation might involve:

   — keeping food at the appropriate temperature by a restaurant until it is ready to be served;

   — an ICT company ensuring the preservation of data integrity by regular back-ups and virus protection;

   — maintaining the shelf life and storage conditions of vaccines;

   — ensuring academic examination papers are not disclosed;

— "clean" operating theatres in hospitals;

b) in the manufacturing sector, in a warehouse for final products, preservation methods can be used to ensure integrity, identification or security of the outputs for particular stages or processes, such as storage, handling or transportation, by controlling such matters as temperature, expiration dates, electrostatic discharge, dust, packaging.

Depending on the nature of the operations it can be necessary to determine preservation methods for any part or component that will be incorporated into the final product (e.g. for manufacturing or assembly) or for equipment or information critical to the provision of a service (e.g. data needed for technical support, following delivery to the customer of a home computer).

There are a number of areas where handling problems can affect the quality of the product or service.

EXAMPLE 1 Some examples are found in the following areas:

— most copper-based metals (e.g. copper, brass and bronze) are susceptible to corrosion from finger-marks;

— liquid-carrying tankers need to be cleaned or decontaminated prior to filling with a different liquid;

— medical specimens need to be handled with special instruments to prevent infection.

Storage requirements vary from industry to industry.

EXAMPLE 2 Examples of storage conditions include cold storage of food; or storage of magnetic media (e.g. video tapes, audio tapes and computer disks) in a non-magnetic environment.

8.5.5 Post-delivery activities

The intent of this subclause is to ensure that the organization fulfils relevant requirements after a product or service is delivered, recognizing that delivery does not necessarily end an organization's responsibility. When determining post-delivery activities the organization should consider known requirements (e.g. statutory and regulatory or customer requirements) and also consider the possibility that the product or service does not perform as expected and further action could be required. The risk of customer dissatisfaction or loss of potential opportunity is increased if the organization does not consider potential and stated post-delivery activities.

Examples of post-delivery activities include:

a) engagement with customers to determine if the products or services were to their satisfaction;

b) on-site installation of equipment and disposal of a customer's old equipment;

c) contractual arrangements such as warranties or technical support;

d) customer access to on-line information related to the delivery of a product or service, e.g. status of flights; frequently asked questions (FAQs);

e) authentication of the product;

f) a computer retailer who provides a technical support service by telephone.

8.5.6 Control of changes

The intent of this subclause is to ensure that the organization reviews and controls changes that occur during the production and service provision, in alignment with the provisions determined during the planning of the quality management system (see ISO 9001:2015[28], 6.3). The determined actions to address such changes should be focused to ensure the outputs, products and services will continue to meet the applicable requirements.

This subclause deals with changes that happen during production and service provision which affect conformity to requirements. The organization should ensure that the integrity of production and service provision is retained by controlling these changes and reviewing actions taken and how this affects the controls implemented in accordance with ISO 9001:2015[28], 8.5.1.

Proposed changes should be examined at all stages of the operation before being introduced.

The reason for changes can vary; for example, a need for change can be initiated by an external provider (e.g. delivery delays or quality issues), an internal issue (e.g. critical equipment failure, recurrent nonconforming outputs) or an external issue (e.g. new or modified customer or statutory and regulatory requirements).

In certain cases, the results of the implementation of the change can become an input to design and development activities (see ISO 9001:2015[28], 8.3.1 and 8.3.6).

The organization should determine the documented information to be retained and the format in which it should be retained; examples include:

a) minutes of the review activities;

b) verification and validation results;

c) description of the change;

d) details of the person(s) authorizing the change (considering the customer as appropriate).

8.6 Release of products and services

The intent of this subclause is to ensure that products and services conform to all applicable requirements before they are delivered to the customer (see ISO 9001:2015, 8.1[28]).

The organization should obtain approval by a relevant authority when the planned arrangements have not been met; in some cases, this could be the customer. The organization should consider establishing criteria for situations where it is necessary to obtain customer approval. In these cases, the requirements for nonconforming outputs could be applied (see ISO 9001:2015[28], 8.7).

The person(s) who authorizes final release of the product or service should be suitably defined by, for example, their job description or authority level, and should be traceable. This can be achieved through the retention of documented information which, for example:

a) gives the signature of the authorizing person;

b) details an overarching authorization for the automated release of products on completion of certain criteria (e.g. automatic electronic payment authorization for an online sale).

8.7 Control of nonconforming outputs

8.7.1 The intent of this subclause is to prevent the unintended delivery or use of non-conforming outputs (at all stages of production and service provision).

When a nonconforming output is determined, the organization should take appropriate action based on its effect on the conformity of the product and service. Actions will vary based on the nature of the nonconforming output such as notifying the customer when a safety or functionality issue is determined, versus a minor issue that is determined during production that can be corrected before delivery.

There are different ways to deal with non-conforming outputs. For ISO 9001:2015, 8.7.1[28], bullets a) to d), the organization might use an approach that applies more than one of the following methods:

a) correcting the nonconformity by repair or rework, or in the case of a restaurant, for example, determining that the wrong meal has been prepared and providing the correct one before delivery;

b) segregation, containment, return or suspension of provision of products and services; organizations should ensure that the products and services are clearly identified in order to prevent the nonconforming output from being inadvertently provided to the customer; this could include some type of physical label or location;

c) informing the customer based on the severity of the nonconforming output or customer requirements; this could be so the customer can take action if the nonconforming output has already been delivered or to direct the organization as to what actions are required; examples of actions to take with customers include:

   — recalls (e.g. due to safety issues, such as incorrect composition of a medicine);

   — suspension or withdrawal of affected products or services (e.g. due to incorrect food product labelling with regards to durability or incorrect pricing in a catalogue or inability to provide a service as described);

   — re-processing;

   — eliminating or reducing the nonconformity to an agreed acceptable level;

   — removing the nonconformity from the process entirely;

d) at times, obtaining authorization under concession could be required (such a concession could be granted by an authorized person in the organization, such as an engineer or supervisor, or by the customer); if such controls are not possible and depending on the nature of the nonconformity, an agreement can be reached with the customer to allow the non-conforming product or service to be used (in this situation authorization should be given by the appropriate person(s) or, where relevant, the customer).

When nonconforming output is corrected after it is detected, it should be verified. This can include inspecting a corrected product or verifying the performance after a correction is made to a service delivery process.

In the case of service delivery processes directly involving the customer, the nonconforming output might only be detected as the service is being provided, or immediately thereafter. The intent of the requirement to take appropriate action still applies, for example, by providing the service again, correcting unintended results or compensating the customer. An example might involve an airline providing assistance, food and/or accommodation as a result of a flight delay, until the flight is able to depart or until the passenger has been rebooked on another flight.

Where further action is needed (for example to respond to complaints and prevent recurrence) the requirements of corrective action should be applied (see ISO 9001:2015, 10.2[28]).

8.7.2 The intent of this subclause is to ensure that the organization retains documented information relating to:

a) nonconforming outputs, at all stages of production and service delivery;

b) actions taken to correct nonconformities;

c) those persons who have the responsibility to approve release of nonconforming products or services.

Retaining documented information can help to ensure that: processes are improved and optimized; corrected work instructions, processes and procedures are detailed for future use; information is communicated to relevant persons both in the organization and externally (see ISO 9001:2015[28], 8.2.1). This documented information can also be used as a basis for analyses of trends in nonconformities.

The organization should ensure that the documented information retained includes details of the nonconformity, the actions taken to correct, mitigate or communicate it, any concessions obtained (e.g.

agreement with the customer that the product or service can be used despite the nonconformity) and who authorized the actions taken.

Examples of documented information can include:

— databases with information about nonconforming outputs;

— completed forms that are retained with the product;

— the production system that keeps information about the provision of the products and services;

— mobile application.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The intent of this subclause is to ensure that the organization conducts monitoring, measurement, analysis and evaluation, to enable the organization to determine if intended results are being achieved.

ISO 9001 requires the organization to determine what needs to be monitored and measured and the methods to be used to analyse and evaluate the performance and effectiveness of the quality management system. When considering the performance and effectiveness of a quality management system, "performance" is the measureable results of the organization and "effectiveness" is the extent to which planned activities are realized and planned results are achieved.

When determining what needs to be monitored and/or measured, the organization should consider the actions required in other clauses, such as for establishing the quality management system and its processes (see ISO 9001:2015[28], 4.4), quality objectives (see ISO 9001:2015[28], 6.2.1), operational planning and control (see ISO 9001:2015[28], 8.1), customer satisfaction (see ISO 9001:2015[28], 9.1.2), analysis and evaluation (see ISO 9001:2015[28], 9.1.3), internal audits (see ISO 9001:2015[28], 9.2) and management review (see ISO 9001:2015[28], 9.3). The organization should then determine how the monitoring, measurement, analysis and evaluation will be carried out, and the resources (see ISO 9001:2015[28], 7.1.5) that will be needed.

The organization should also decide what documented information will need to be retained as evidence of the results of monitoring, measurement, analysis and evaluation. This documented information is typically the same documented information that is required in other ISO 9001 clauses, such as those for management review.

9.1.2 Customer satisfaction

The intent of this subclause is to focus on monitoring customer feedback to evaluate customer satisfaction and to determine opportunities for improvement. It provides an approach for understanding customers' perceptions about the products and services of the organization and whether needs and expectations have been met.

Organizations should consider different methods of obtaining information based on customer type (e.g. surveys, organization-to-organization, organization to customer, public service, government, e-commerce). Organizations will need to determine the method(s) they wish to use, depending on the nature of their operations. These methods can include, but are not limited to:

a) opinion surveys;

b) customer communication (see ISO 9001:2015[28], 8.2.1);

c) customer data on delivered products or services quality;

d) market-share analysis;

e) compliments;

f) complaints;

g) warranty claims;

h) dealer reports;

i) social media, such as web sites and message boards;

j) invoice queries;

k) published information, such as in newspapers or journals.

The organization should determine the customers from which it wants to request customer satisfaction feedback and how it will monitor the information. The organization can choose to request feedback from every customer at the completion of a transaction or use a representative sample based on a target number of sales, customers with recurring orders, or new customers. This can be done on an ongoing basis or at a specific frequency established by the organization.

The organization should be able to determine the degree of customer satisfaction after the results are analysed and evaluated and take action based on this information. This information should be an input to management review and be used to determine if actions are necessary to improve customer satisfaction.

9.1.3 Analysis and evaluation

The intent of this subclause is for the organization to analyse and evaluate data and information from the results of monitoring and measurement in order to determine if processes, products and services meet requirements and to determine any needed actions and opportunities for improvement.

The organization should determine the appropriate data to review. Data selection should ensure that the results of analysis and evaluation can be established to evaluate the performance and effectiveness of the quality management system and determine the need for any improvements.

Examples of data sources can include, but are not limited to:

a) product: yield; conformity to specific requirements (e.g. customer, statutory, regulatory); rates of nonconformities [e.g. parts per million (PPM)]; scrap and rework; on-time delivery; fulfilment of order;

b) service performance: queuing times; indication of resolution of customer issues; ease of access; cleanliness; housekeeping; friendliness;

c) results from monitoring of customer perception;

d) delivery of projects to plan (e.g. budget and timing);

e) review of action items on risks and opportunities (e.g. meeting minutes);

f) on-time delivery and quality (e.g. rejects) for external providers;

g) status of quality objectives.

The organization should consider how frequently it will analyse and evaluate data that will help determine areas for improvement. This can be dependent on the ability of the organization to retrieve information electronically versus manual preparation of data. The organization should ensure that methods and data quality (e.g. representative, unbiased, complete, accurate, capable) provide useful information for managerial decisions. Statistical techniques can be useful tools for the analysis and evaluation processes.

The output from analysis and evaluation is frequently in the form of documented information such as trend analyses or reports, balanced scorecards, dashboards, and becomes an input to management review or meetings that consider the output. For this reason, it should be in a format that allows a determination to be made of whether actions are needed to improve the quality management system. While analysis and evaluation are frequently related to management review, the organization should determine the appropriate frequency for evaluating and analysing the information. Some organizations could choose to conduct this analysis more frequently, such as through daily meetings.

9.2 Internal audit

9.2.1 The intent of the clause is to obtain information through internal audits about the performance and effectiveness of the quality management system from an impartial view, to ensure that planned arrangements have been completed and that the quality management system is effectively implemented and maintained.

Internal audits can be used to determine if the quality management system conforms to the requirements of ISO 9001 and the requirements of the organization. Audit methods should include direct observation of the process, interviews with relevant persons, and the examination of documented information (such as internal procedures, drawings, specifications, standards; customer requirements; statutory and regulatory requirements; and in enterprise management systems). While the organization should always try to ensure that its quality management system complies with all the applicable requirements of ISO 9001, there is no requirement for every clause of ISO 9001, or process in the quality management system, to be evaluated during every audit.

9.2.2 The intent of this subclause is to ensure that the organization establishes, implements and maintains an audit programme(s). In some cases, where the organization has multiple sites, the organization can set up an audit programme for each specific location. The audit programme establishes arrangements for a set of one or more audits planned for a specific timeframe and should be directed towards ensuring the performance and effectiveness of the quality management system.

The audit programme should indicate how frequently the organization will conduct audits (e.g. monthly, quarterly, annually, or according to a schedule that differs for areas or processes over the course of a year). When determining the frequency, the organization should apply risk-based thinking and consider how often the process is performed, how mature or how complex the process is, any changes in the process, and the objectives of the audit programme. For example, more mature processes are likely to require less frequent internal audits. More complex processes can require more frequent internal audits. A list of inputs to consider when planning audits includes, but is not limited to:

a) importance of the processes;

b) managerial priorities;

c) performance of the processes;

d) changes affecting the organization;

e) results from previous audits (e.g. history of problems);

f) trends in customer complaints;

g) statutory and regulatory issues.

The organization's internal audit programme(s) should also define the methods to be used for audits; these methods can include interviews, observations, sampling and information reviews. As a best practice, the organization should plan and conduct audits according to the requirements of its quality management system, by project or process, rather than by the specific clauses in ISO 9001.

When assigning persons to conduct audits, the organization should ensure objectivity and impartiality of the audit process. In some cases, specifically in smaller organizations or areas of the organization where specific job knowledge is required, it can be necessary for a person to audit their own work. In

this situation, the organization might have the internal auditor work with a peer, or have the results reviewed by a peer or a manager, to ensure results are impartial. The organization could also consider obtaining resources from an external provider such as a university, external auditor, or another organization.

EXAMPLE A plumber and an electrician can conduct audits on each other or help the other one out, or a cleaning company could require its administrative staff to audit the cleaning process since they are not directly involved in that particular task.

As part of the planning activity, the organization should determine the criteria and scope for internal audits. The audit criteria can be defined by specific standards or requirements and the audit scope can include specific departments, product lines, processes, or facilities. It can be helpful for the organization, if it has implemented a management system addressing more than one management system standard with similar requirements, to conduct combined audits (e.g. for an integrated or combined management system) to reduce redundancy. This information is typically presented in an audit plan (i.e. the detailed plan for conducting a specific audit).

After the internal audit is completed, the results should be reported to relevant managers. Based on these results, appropriate correction and corrective actions can be necessary. An organization can choose to establish criteria for when a corrective action is required, based on factors such as the severity of a nonconformity. Typically, the organization establishes a time to respond to and correct nonconformities and to take corrective actions, to ensure they are effectively implemented in a timely manner.

To add value during internal audits, it can be possible to observe conditions that meet requirements, but might represent a potential weakness in the quality management system; alternately, improvement opportunities could be determined based on experiences from other internal audits and practices observed in other processes or locations. In such cases, if an organization includes this information in the audit report, it can provide managers with the information to decide if it is appropriate to initiate action for improvement.

The organization is required to retain documented information to provide evidence of the audit programme being implemented and the audit results. Examples of audit results can include audit reports, evidence of corrections or corrective actions taken (e.g. training, updated documented information). The results of internal audits are needed as an input to management review.

9.3 Management review

9.3.1 General

The intent of this subclause is to ensure that top management conduct management reviews. This is an activity that top management should conduct in alignment with the strategic direction of the organization. Its purpose is to review information on the performance of the quality management system in order to determine if it is:

a) suitable – does it still fit its purpose?

b) adequate – is it still sufficient?

c) effective – does it still achieve the intended results?

Management review should be conducted at planned intervals; this could be daily, weekly, monthly, quarterly, semi-annually or annually. Some management review activities may be carried out by various levels of the organization, provided the results are made available to top management. It is not required that all the inputs to management review be addressed at one time, but instead they may be addressed during sequenced management reviews; the organization should address how it will ensure that all the ISO 9001 management review requirements are met. The organization may conduct management reviews as a standalone activity or in a combination of related activities (e.g. meetings, reports).

The timing of management reviews can be scheduled to coincide with other business activities (e.g. strategic planning, business planning, annual meetings, operations meetings, other management system standards' reviews) to add value and to avoid redundant multiple meetings.

EXAMPLE A travel agency decides to have a management review the day before its six-monthly strategic meeting to get all the inputs necessary for planning the budget, and to ensure that the quality objectives are in alignment with the agency's strategic direction.

9.3.2 Management review inputs

The intent of this subclause is to establish the inputs that an organization needs to consider in evaluating the performance and effectiveness of the quality management system.

Management review inputs are directly related to the requirements of other clauses in ISO 9001; this includes the analysis and evaluation of data (see ISO 9001:2015, 9.1.3[28]). The inputs should be used to determine trends in order to make decisions and take actions related to the quality management system. For ISO 9001:2015[28], 9.3.2, bullets a) to f), the following management review inputs should be considered:

a) status of actions from previous management reviews;

b) changes in external and internal issues (see ISO 9001:2015[28], 4.1);

c) information on the performance and effectiveness of the quality management system:

   1) customer satisfaction (see ISO 9001:2015[28], 9.1.2) and feedback from other relevant interested parties (see ISO 9001:2015[28], 4.2);

   2) the extent to which quality objectives have been met (see ISO 9001:2015[28], 6.2);

   3) process performance and conformity of products and services (see ISO 9001:2015[28], 4.4 and 8.6);

   4) nonconformities and corrective actions (see ISO 9001:2015[28], 10.2);

   5) monitoring and measurement results (see ISO 9001:2015[28], 9.1.1);

   6) audit results, including, as appropriate, the results of internal (see ISO 9001:2015[28], 9.2), customer, regulatory body, or certification body, audits;

   7) performance of external providers (see ISO 9001:2015[28], 8.4);

d) adequacy of resources (see ISO 9001:2015[28], 7.1);

e) effectiveness of actions taken to address risks and opportunities (see ISO 9001:2015[28], 6.1);

f) opportunities for improvement (see ISO 9001:2015[28], 9.1.3).

An organization can include additional items in management review (such as new product introduction, financial results, new business opportunities, or relevant information about problems or opportunities from the field or the market where the products are used or the services are provided), in order to determine if the organization is and will be able to continue achieving its intended results. Management review can also be extended to cover other requirements in ISO 9001 for monitoring and reviewing information (such as in ISO 9001:2015[28], 4.1 and 4.2).

9.3.3 Management review outputs

The intent of this subclause is to ensure that management reviews provide outputs and information about the performance and effectiveness of the quality management system, and on any decisions and actions needed.

The outputs of management reviews should include decisions and actions relating to opportunities for improvement (see ISO 9001:2015[28], 10.1), changes needed to the quality management system (see ISO 9001:2015[28], 6.3), and resource needs (see ISO 9001:2015[28], 7.1). The status of actions identified during a management review should be included as an input to the next management review activity. Monitoring can help to ensure that actions are taken on a timely basis.

The organization should retain documented information as evidence of results of management review. Examples of documented information include presentations, meeting minutes and reports.

10 Improvement

10.1 General

The intent of this subclause is to ensure that the organization determines opportunities for improvement, as well as plans and actually implements actions in order to achieve the intended results and to enhance customer satisfaction. Improvements can help the organization to keep meeting customer requirements and expectations by improving its products and services, correcting or preventing undesired effects, and improving the performance and effectiveness of the quality management system.

There are different methods to conduct improvement, such as:

a) taking actions to avoid the recurrence of nonconformities;

b) small-step ongoing improvement activities conducted within existing processes, products or services;

c) projects which can lead to significant changes to existing processes, the implementation of new processes, products or services, or the introduction of disruptive new technologies or innovations.

The requirements for corrective action (see ISO 9001:2015, 10.2[28]) help to determine and eliminate the causes of nonconformities, to prevent their recurrence.

Continual improvement (see ISO 9001:2015, 10.3[28]) should be conducted to enhance performance and to implement agreed solutions that are intended to achieve positive benefits.

Improvement actions can be performed on processes, products and services as well as on the quality management system.

10.2 Nonconformity and corrective action

10.2.1 The intent of this subclause is to ensure that the organization manages nonconformities, and implements corrective action, appropriately.

When a nonconformity occurs (including those arising from complaints; from identified nonconforming outputs [see ISO 9001:2015, 8.7[28]]; problems arising from external providers or other relevant interested parties; audit results; or the effects of unplanned changes), the organization should take action to investigate what has gone wrong, to correct it if possible, and to avoid similar issues from recurring in the future. The organization should seek to eliminate permanently the causes and consequent effects of problems that could have a negative impact on its:

a) results;

b) products, services, processes or quality management system;

c) satisfaction of customers.

Potential sources of nonconformities and types of nonconformities include, but are not limited to:

— internal or external audit findings (see ISO 9001:2015, 9.2[28]);

— monitoring and measuring results (e.g. inspection, product or service defects);

— nonconforming outputs (see ISO 9001:2015, 8.7[28]);

— customer complaints;

— noncompliance with statutory and regulatory requirements;

— problems with external providers (e.g. on-time delivery, incoming inspection);

— employee identified problems (e.g. through suggestion boxes);

— observations from a superior or responsible person or process patrols;

— warranty claims.

The organization should take action to control or correct any nonconformity. This can be achieved by containing the problem while investigations continue. For example, the organization might need to contact customers or external providers to make them aware of a nonconformity and to provide information about the potential or actual effects on the product provided or service delivered.

When evaluating the action needed for a nonconformity the organization could consider that there might be instances where the cause of a nonconformity cannot be eliminated, therefore, the organization should consider taking actions to be able to detect and minimize the effects of the nonconformity if it were to occur again.

The organization should review and analyse a nonconformity to determine its cause and whether it exists elsewhere, or is likely to recur or potentially occur in another process and/or part of the organization. The organization should determine the extent of the actions that need to be taken, based on the potential effect of the nonconformity. The organization should implement any needed actions based on this review. This could be accomplished by using various methods such as, but not limited to: root cause analysis; eight disciplines (8Ds) problem solving; 5-why method; FMEA; or cause-and-effect-analysis diagrams.

The organization should review the effectiveness of any corrective actions by confirming (through evidence) that the actions have been implemented or correction taken and as a result the nonconformities have not recurred. This might be accomplished by observing the performance of processes or reviewing documented information. In order to ensure that effective implementation can be verified, the organization should allow an appropriate amount of time to pass, prior to reviewing the actions taken; this will vary depending on the complexity and resource needs (e.g. capital equipment purchases) of the actions necessary to resolve the nonconformity.

The organization should determine if the effects of corrective action taken in one area could potentially cause adverse effects in another area of the organization, and plan any necessary mitigating actions, prior to implementation.

After the review of corrective actions, the organization should consider whether there are risks or opportunities that have not been determined previously, or if the actions for risks and opportunities were not effectively addressed during planning (see ISO 9001:2015, 6.1[28]). Updates should be made to this planning as necessary.

When taking action to address the cause of a nonconformity, the organization should also give consideration to the need for changes to processes within the quality management system.

10.2.2 The intent of this subclause is to ensure that the organization retains documented information in order to provide evidence that correction or corrective action has been completed as required.

The organization should retain appropriate documented information to show what correction or corrective actions were taken, including details relating to the nonconformity (e.g. nonconformity statement, severity of the nonconformity, root cause analysis, planned correction and corrective action); examples include corrective action forms or databases.

The organization should also retain documented information of the results of any corrective action taken. This could include evidence demonstrating the actions such as data collection, testing, reports, changes made to the documented information, performance and effectiveness of the quality management system.

10.3 Continual improvement

The intent of this subclause is to ensure that the organization continually improves the suitability, adequacy and effectiveness of its quality management system.

Continual improvement can include actions to increase the consistency of outputs, products and services, in order to increase the level of conforming outputs, improve process capability and reduce process variation. This is done in order to enhance the organization's performance and benefit its customers and relevant interested parties.

The organization should consider the results from analysis and evaluation (see ISO 9001:2015, 9.1.3[28]) and management review (see ISO 9001:2015, 9.3[28]) to determine if continual improvement actions are needed. The organization should consider those actions necessary to improve the suitability, adequacy and effectiveness of the quality management system.

There are several methodologies and tools that the organization can consider to conduct continual improvement activities (kaizen). Examples can include, but are not limited to: Six Sigma methodologies; “lean” initiatives; benchmarking and the use of self-assessment models.

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